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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,967	08/01/2003	Alexander Hillisch	GULDE-0002	2520
23599	7590	08/05/2005	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			BADIO, BARBARA P	
		ART UNIT	PAPER NUMBER	
			1617	

DATE MAILED: 08/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/631,967	HILLISCH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Barbara P. Badio, Ph.D.	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 and 3-16 is/are rejected.
- 7) Claim(s) 2 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**First Office Action on the Merits**

***Specification***

1. The disclosure is objected to because of the following informalities: The present disclosure lacks a "Brief Description of the Drawings".

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 8-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims recite a "use" without setting forth any steps involved in the process and, thus, results in an improper definition of a process, i.e., results in a claim that is not a proper process claim under 35 USC § 101 (see MPEP § 2173.05(q)).

***Claim Objections***

4. Claims 3 and 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 3 recites X can be "a straight-chain or branched or unsaturated alkyl radical with 1-4 carbon atoms". However, parent claim 1 recite "an alkyl radical with 1 or 2 carbon atoms".

Claim 6 recites compounds not encompassed by general formula I as defined by the present invention. For example, 4-[4'-Bromo-17beta-hydroxy-17alpha-trifluoromethyl-3-oxoestra-4,9-dien-11beta-yl]benzaldehyde-1-(E)-oxime. R3, i.e., 17alpha-position, as defined by parent claim 1 cannot be a CF<sub>3</sub> group.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claim recites the use of "prodrugs" of estrogen. However, the present specification lacks definition of said prodrugs and, thus, does not convey to the skilled artisan in the art that applicant had possession of the claimed invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 6 and 8-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite for the following reasons:

(a) Claim 6 recites compounds of general formula I but does not define said formula I. Therefore, the instant claim is indefinite.

(b) Claims 8-16 recite a "use" without any active, positive steps delimiting how this use is actually practiced and, thus, it is unclear what process is encompassed by the claimed invention (see MPEP § 2173.05(q)).

For the purpose of prior art rejection, the instant claims are interpreted as being drawn to compositions comprising the claimed compounds.

(c) Claim 14 recites "prodrugs" of estrogen. The present specification lacks definition of what applicant intends by the use of the word "prodrug" and, thus, the metes and bound of the claimed invention is indefinite.

(d) Claims 15 and 16 recite "estrogen" or "estrogen-3-sulfamate", respectively. However, there is insufficient antecedent basis for the limitations in the claims and, thus, the claimed invention is indefinite.

#### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 3-5 and 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Schubert et al. (WO 99/45023, see US 6,365,582 for English translation).

Schubert teaches 11 $\beta$ -benzaldoxime-estra-4,9-diene derivatives such as 4-[17 $\beta$ -hydroxy-17 $\alpha$ -(hydroxymethyl)-3-oxoestra-4,9-dien-11 $\beta$ -yl]benzaldehyde-(E)-oxime and their use in the preparation of S-substituted 11 $\beta$ -benzaldoxime-estra-4,9-diene-carbonic acid thioesters (see the entire article, especially formula (II), page 12 and page 30, stage C or '582, col. 7, lines 34-50 and col. 15, lines 21-22 for English translation). The compound and composition taught by the reference are encompassed by the instant claims.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1 and 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schubert et al. (WO 99/45023, see US 6,365,582 for English translation).

Schubert teaches 11 $\beta$ -benzaldoxime-estra-4,9-diene derivatives such as 4-[17 $\beta$ -hydroxy-17 $\alpha$ -(hydroxymethyl)-3-oxoestra-4,9-dien-11 $\beta$ -yl]benzaldehyde-(E)-oxime and

their use in the preparation of S-substituted 11 $\beta$ -benzaldoxime-estra-4,9-diene-carbonic acid thioesters (see the entire article, especially formula (II), page 12 and page 30, stage C or '582, col. 7, lines 34-50 and col. 15, lines 21-22 for English translation).

The instant claims differ from the reference by reciting additional compounds not exemplified by the reference. However, the selection of any of the species of the genus taught by the reference, including those of the instant claims, would have been obvious to the skilled artisan. The motivation to make additional compounds as taught by the reference, including those of the instant claims, is based on the teaching of the reference that the compounds are useful starting materials for the production of S-substituted 11 $\beta$ -benzaldoxime-estra-4,9-diene-carbonic acid thioesters having reduced antiglucocorticoid action.

13. Claims 1 and 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schubert et al. (US 5,693,628).

Schubert et al. teach 11 $\beta$ -benzaldoxime-estra-4,9-dienes, such as, 17 $\alpha$ -chloromethyl-11 $\beta$ -[4-(hydroximinomethyl)phenyl]-17 $\beta$ -hydroxy-estra-4,9-diene-3-on, having strong antigestagenic effects with reduced glucocorticoid activity (see the entire article, especially Abstract, col. 3, line 51 – col. 6, line 38; col. 10, lines 9-67).

The instant claims differ from the reference by reciting additional compounds not exemplified by the reference. However, the selection of any of the species of the genus taught by the reference, including those of the instant claims, would have been obvious to the skilled artisan. The motivation to make additional compounds as taught by the

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reference, including those of the instant claims, is based on the teaching of the reference that the compounds are superior antigestagenic agents with reduced glucocorticoid activity (see especially col. 10, lines 9-18).

It is noted that  $17\alpha$ -chloromethyl- $11\beta$ -[4-(hydroximinomethyl)phenyl]- $17\beta$ -hydroxy-estra-4,9-diene-3-on is proviso out of the claimed invention. However, the reference teaches the equivalence between chlorine and other halogens (see definition of  $R^3$  as taught by the reference, col. 4, lines 24-29). Thus, the substitution of fluorine, bromine or iodine for chlorine as exemplified by the prior art compound would be *prima facie* obvious.

***Allowable Subject Matter***

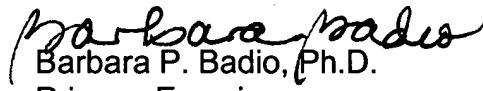
14. Claim 2 is objected to as being dependent upon a rejected base claim.

***Telephone Inquiry***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
August 3, 2005